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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,189	06/03/1999	MASATAKA KINJO	990360/LH	2516
1933	7590	06/30/2005	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC			TUNG, JOYCE	
220 5TH AVE FL 16			ART UNIT	
NEW YORK, NY 10001-7708			PAPER NUMBER	
			1637	
DATE MAILED: 06/30/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/325,189

Applicant(s)

KINJO, MASATAKA

Examiner

Joyce Tung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8, 39, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-8, 39, and 42-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The applicant's response filed May 10, 2005 to the Office action has been entered.

Claims 1-4, 7-8, 39, 42-43 are pending.

1. The rejection of claims 1-4, 7-8, 39 and 42-43 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment.
2. The rejection of claims 1-5, 7-8, 39 and 42-43 under 35 U.S.C. 103(a) as being unpatentable over Salituro et al. (6,391,544, issued May 21, 2002) in view of Eigen et al. (5,807,677, issued September 15, 1998) and in view of McCabe (PCR Protocols: A Guide to Methods and Applications, 1990, pg. 76-83) is withdrawn because of the amendment.

### **NEW GROUNDS OF THE REJECTIONS**

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claims 1-4, 7-8, 39, 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - a. Claims 1-4, 7-8, 39, 42-43 are vague and indefinite because it is unclear what is the definition for the phrase "number". Clarification is required.
  - b. Claims 1-4, 7-8, 39, 42-43 are vague and indefinite because of the phrase "the other one" which has not antecedent basis.

***Allowable Subject Matter***

5. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 1-4, 7-8, 39, 42-43, no prior art has been found teaching or suggesting a method of analyzing a target nucleic acid by applying the primer which has lower number than another primer and is labeled comprising determining a number of cycles of the nucleic acid amplification reaction until the labeled primer has been consumed and quantifying an initial amount of the target nucleic acid on the basis of cycles of the nucleic acid amplification reaction.

The closest prior art is the reference of Salituro et al., Eigen et al. and McCabe. Salituro et al. disclose a method of detecting a target sequence which involving a labeled primer, which has lower concentration than another primer, Eigen et al. disclose fluorescence correlation spectroscopy (FCS) and advantage of using the technique in PCR method and McCabe discloses an asymmetric PCR in which during an initial 15-25 cycles, double stranded DNA is generated and as the low concentration primer becomes depleted, further cycles generate an excess of one of the two strand. However, the combination of the references does not render the instant invention because there is no motivation to quantifying an initial amount of the target nucleic acid on the basis of cycles of the nucleic acid amplification reaction as the labeled lower number of the primer is consumed.

**Summary**

6. No claims are allowable.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 571 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0982. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung JT  
June 26, 2005

  
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